

The Declaration of co-inventor Dr. J. Todd Abrams with Exhibits, also accompanies this Amendment in support of the patentability of the present invention.

By this amendment, Applicants have added claims 31-38 for a method of treating Alzheimer's disease which are not specific to a bacterium. It is submitted that these newly presented claims are not shown or suggested by the cited art and are thus patentable thereover.

Claims 8-17 and claims 31-38 are currently pending.

Claims 1-7 were cancelled without prejudice to filing a continuing application on these claims.

Claims 8-17 stand rejected under 35 U.S.C. § 103 as being unpatentable over Shor in view of Koskiniemi *et al.* Applicants respectfully traverse this rejection.

Independent claim 8 is directed to a method of treating Alzheimer's disease in a mammal having a *Chlamydia pneumoniae* infection by administering a therapeutic amount of an anti-microbial agent.

Independent claim 15 is directed to a method of treating Alzheimer's disease in a mammal having a *Chlamydia pneumoniae* infection by administering a therapeutic amount of an anti-microbial agent and an anti-inflammatory agent.

Applicants respectfully submit that, under the present case law regarding inherency, Shor does not render claims 8-17 *prima facie* obvious under 35 U.S.C. §103(a). Shor discloses treatment of arterial *Chlamydial* granuloma by administering certain compounds. Shor makes it clear, at column 2, lines 1-2, that tetracyclines and macrolides were well-known art-recognized compounds effective for treatment of *Chlamydia*

*pneumoniae* respiratory infections. Based on these teachings, one of ordinary skill in the art would not have applied the teachings of Shor to treat Alzheimer's disease because, until the present invention, it was not known that *C. pneumoniae* infection in the CNS was involved in AD pathology such that treating the Chlamydial infection would treat Alzheimer's. See Dr. Abrams' Declaration in this regard.

These surprising teachings were heretofore unknown and no amount of additional observation of the effects of macrolides and anti-inflammatory agents in arterial *Chlamydial* granuloma patients would have revealed that such treatment would be effective against Alzheimer's disease. It is respectfully submitted that the correlation between *Chlamydial* infection in the CNS and Alzheimer's disease could not be predicted based upon the teachings of Shor, alone or in combination with any other cited art.

Although it may have been, *arguendo*, inherent that treatment of a systemic *Chlamydia* infection might treat Alzheimer's disease, such result was not known as was not obvious to one of ordinary skill based upon the teachings of Shor. That is, to paraphrase the *Marshall* Court, if anyone ever improved from Alzheimer's disease by following the teachings of Shor, it was an unrecognized accident. *Marshall*, 198 USPQ at 346. Thus, to say that this would have been obvious to one of ordinary skill armed with the teachings of Shor is impermissible hindsight.

Because Shor does not teach or suggest all of the claims limitations, and because there would have been no motivation to apply the teachings of Shor, nor any reasonable expectation of success in doing so, to treat Alzheimer's disease, Shor cannot render claims 8-17 *prima facie* obvious under 35 U.S.C. §103(a). Further, even assuming,

*arguendo*, that the method of Shor would treat a *C. pneumoniae* infection in the CNS, it would not have been obvious to one of ordinary skill that the treatment would thereby treat Alzheimer's disease. Therefore, for the above-stated reasons, Shor cannot render claims 8-17 obvious under 35 U.S.C. §103(a) and this rejection should be reconsidered and withdrawn.

The Examiner contends that it would have been obvious to one of ordinary skill in the art to treat an Alzheimer's disease patient having a *Chlamydia pneumoniae* infection with anti-Chlamydia drugs. Even assuming, *arguendo*, that this statement is correct, this is not dispositive of the issue under consideration. That is, whether it was obvious to treat a *Chlamydia* infection in the lungs of a patient using known anti-chlamydia drugs, is not relevant where Applicants are claiming a method of treating a *C. pneumoniae* infection in the CNS where it was not known, prior to Applicant's invention, that *C. pneumoniae* infection could be localized in the CNS, especially where the patient does not exhibit symptoms of multiple sclerosis or meningoencephalitis. This is because, prior to Applicant's discovery that *C. pneumoniae* infection in the CNS is involved in Alzheimer's pathology, it would not have been obvious to the skilled artisan to look for, much less to treat, a *C. pneumoniae* infection in the CNS where the patient does not present MS or meningoencephalitis symptoms.

Therefore, art-recognized methods for treatment of *C. pneumoniae* infection cannot render the present invention *prima facie* obvious where it was not known that *C. pneumoniae* infection could be present in the CNS and, with regard to claims 8-17, where it was not known that *C. pneumoniae* infection in the CNS plays a role in Alzheimer's

disease. Assuming, for argument's sake, that it would have been obvious that such an infection would be present in the CNS and it would have been even more surprising that treating a *C. pneumoniae* infection in the CNS would treat Alzheimer's disease.

Thus, Applicants submit that the presently claimed invention is not shown or suggested by the art of record and that it is patentable thereover.

It is submitted that there is no motivation to combine the cited Koskiniemi reference with Shor, because there is no deficiency or motivation in Shor which would lead one to consider Koskiniemi. As set forth in Dr. Abram's Declaration, standard treatment of a *C. pneumoniae* respiratory infection with antibiotics would most likely be insufficient to observe improvement in Alzheimer's patients because this bacteria is difficult to clear from tissues and would likely require 3 months of combined antibiotic therapy to see real improvement. Thus, someone attempting to merely eradicate *C. pneumoniae* using standard treatment would not arrive at the success of the present invention in treating Alzheimer's disease. This further demonstrates that the cited prior art does not show any motivation, alone or in combination, to show or suggest the present invention.

As further described in Dr. Abram's Declaration, several scientists and clinicians have remarked that there is "no evidence that infection plays a role in Alzheimer's disease," this is a quote after a paper on the present invention was published. This statement is attributed to Dr. Selko, who by all measures is an expert in the field of the treatment of Alzheimer's disease. Thus, it is submitted that the present invention is not an obvious modification of the prior art.

For these reasons, and for the reasons set forth previously elsewhere,  
Applicants' respectfully submit that all the pending claims are patentable over the cited art.

Favorable reconsideration of the amended application is respectfully  
requested.

Respectfully submitted,

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